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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
BEFORE THE HONORABLE EDWARD M. CHEN, JUDGE

UNITED STATES OF AMERICA, ex rel. CAMPIE et al.,	)	
Plaintiffs,	)	
VS.	)	NO. C 11-941 EMC
GILEAD SCIENCES INC., et al.,	)	
Defendants.	)	San Francisco, California Tuesday October 21, 2014 2:51 p.m.

TRANSCRIPT OF PROCEEDINGS

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(Appearances continued, next page)

APPEARANCES, CONTINUED:

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TUESDAY, OCTOBER 21, 2014 2:51 P.M.

P R O C E E D I N G S

THE CLERK: Calling Case CR-11-00941, United States versus Gilead Sciences.

Counsel, please come to the podium and state your name for the Record.

MR. FRIEDMAN: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MR. FRIEDMAN: My name is Andy Friedman from Bonnett, Fairbourn, Friedman & Balint. And I represent the relators in this case.

THE COURT: All right. Thank you, Mr. Friedman.

MR. POSNER: Good afternoon, Your Honor. Ethan Posner, along with my colleague Haywood Gilliam (Indicating), for the Defendant in this case, Your Honor.

THE COURT: All right. Thank you, Mr. Posner.

MS. WINSLOW: And Your Honor, Sara Winslow for the United States, if the Court has questions for the government.

THE COURT: Great.

MR. FRIEDMAN: I shall also point out that my co-counsel Ingrid Evans and Elliot Wong are here as well (Indicating).

THE COURT: Thank you, Counsel.

The first question is the question about the sealing of the records. And I guess -- you know, I have some sense of

what it is that's been filed under seal, but it's not clear to me that we are going need to refer with any degree of specificity to those other than to the general context, but I have -- I would guess I want to hear from you whether you still think that we need to seal this hearing.

MR. FRIEDMAN: Your Honor, I have prepared some slides which reference some of the sealed exhibits.

THE COURT: Uh-huh.

MR. FRIEDMAN: I believe that I can present my argument with general references that will not disclose any purportedly confidential information, but Your Honor of course, and your clerk, if appropriate, can view the information. It simply will not be part of the record.

So I don't believe there will be a need to seal --

THE COURT: And we have the capability of having just my monitor and the clerk's monitor without the public monitor.

MR. FRIEDMAN: And Your Honor, when I said "slides," actually it's printed documents.

THE COURT: Oh, oh, oh. I thought you were going to put it on the ELMO or something. Okay. So one thing we can do is proceed until and unless we get to a point where we start to get into some specifics, at which point I can take action to seal.

Do you have a different view?

MR. POSNER: No, Your Honor. I intend to refer to

the exhibits; they support our motion to dismiss. I think I can probably do that -- I mean, from my perspective I think I can probably do that in a way at that protects the trade-secret and confidential information. Obviously, I don't know how Plaintiffs' Counsel is going to proceed.

I am planning on discussing the exhibits at some length, but believe that I can do so for purposes of this hearing in a way that navigates around the issues we have been talking about.

THE COURT: All right. Why don't we try to proceed on that basis. And then, you know, if we start to get into, of necessity, some details that are matters under seal then we can take action at that point. I'll leave it to you to alert me if we get into that danger zone.

I'm, frankly, kind of more interested -- I guess you have a detailed factual presentation you want to make. But I'm kind of more interested in some of the general legal principles, particularly, you know, the -- the cases, the *Hendow*, the *Ebeid*, the *Omnicare* cases, and the whole question about what happens when alleged misrepresentations are made to the FDA; can you fashion an FCA claim out of that?

I don't know if that requires us to get into the -- too much into the weeds because there are some larger legal and policy implications that -- that's the first thing I want to attack. I think those --

MR. POSNER: Would you like me to be in there, Your Honor?

THE COURT: Yeah, but let me just -- let me tell you some initial thoughts and questions that I have, and then you can respond to it.

MR. POSNER: (Nods head)

THE COURT: First of all, you know, the paradigm cases we all know is where there is a miscertification, misrepresentation to the payor, to the paying agency. And in large part I think that's what *Hendow* and *Ebeid* and most of those cases are -- almost all of the cases are along those lines.

As I understand it, there is a strain of that here. I want to put that aside. I'm not talking about worthless goods and that -- that's kind of a second tier. But the first question, the first question is stemming from the alleged misrepresentations to the FDA to get approval or to avoid recall or some other remedial action, which then sequentially led to the selling of these drugs, basically, to Medicare, Medicaid, VA, et cetera.

That, at least in the main, seems to involve an alleged misrepresentation or omission made to kind of like a licensing agency, a gatekeeping agency, which then leads to a transaction in which money is paid to the party that engaged in the misrepresentation.

So there is a different chain of events here, which gives rise, as *the Omnicare* case points out, to a host of sort of legal questions, factual questions, and policy questions. And, one of those is that I don't think it's disputed.

And I think in the *Hopper versus Anton* case, there's a statement about the false-certification theory, that you have to show the false statement caused the government to make a payment. I don't think that's a novel concept. I think it's clear.

And so when a misrepresentation that is a *sine qua non* of a payment is made directly to the paying agency, there is not much of a question of causation. I mean if it's a requirement and representation was made, it was false, I think one can fairly assume that the government would not have paid under those circumstances.

But here, there's a chain of causation that is a little tricky because it's like, well, had the FDA known about these various issues and violations and misrepresentations, the FDA might not have approved the drug, might have recalled the drug, may have taken it off the market, may have done something which then would have resulted in the non- -- in the transaction or not -- resulted in a non-transaction, and therefore, non-payment to Gilead.

The problem I have there and I think the problem that perhaps bothered the Fourth Circuit is that: Well, how do we

know? Given the range of remedies and things that the FDA can do, short of a recall, short of a denial, there are lots of other remedial steps, perhaps. Or they might find that it wasn't material enough to prevent the actual approval of the drug.

How do we know in that chain of causation what the FDA would have done? Seems to me what the FDA does is in one of those links in that chain. And how do we know that, and how is that going to be proven if we get to a trial?

Do we have to put on the administrator or the FDA, or experts from the FDA? And say, "Well, had we known this, we probably would have, rather than suspending the process, or calling for further investigation or putting -- requiring different quality control things, we would have taken it off the market"? Or whatever. How do we know that?

That's what I think bothered the Fourth Circuit, is that this chain of causation is not directly "I lied to you and you paid." Now it's like "I lied to you, and then you let me go, so then that led to my payment eventually."

And when that third party is a complicated regulatory scheme, that I don't know how we would determine sitting here as an FCA court, what would have happened. That's the core of the problem that I see with that claim.

MR. FRIEDMAN: Your Honor, may I hand up the documents, because I may need or want to refer to them as I

answer Your Honor's question?

THE COURT: Yeah. Yeah.

(Document handed up to the Court)

MR. FRIEDMAN: Your Honor, if I might, before I get to *Omnicare* I would like to start with the Ninth Circuit law in *Hendow*, which I think provides the most closely analogous scenario. The other cases in the Ninth Circuit really don't deal to any extent with the analytical framework. And, there are three aspects to *Hendow*, I think, that help answer Your Honor's question.

Defendants repeat over and over again that false certification -- in a false-certification case -- and in this case we have alleged claims both under the false-certification theory and the promissory-fraud theory, and they say that *sine qua non* or the requirement that it be a condition of payment is somehow controlling.

We don't dispute that there is language to that effect in Ninth Circuit cases. But what *Hendow* explains is how that applies in a case like this. As Your Honor knows, the Defendant in *Hendow* was the University of Phoenix. And, the relator was a former enrollment counselor at the University of Phoenix. And the relator alleged that the defendant in that case violated the ban on incentive compensation for providing compensation based upon a number of recruits or students enrolled. And, the claims for payment in that case were made

under the Title IV, the Pell grants, and under the federal family education loan program.

Importantly, there was no allegation in *Hendow* that the defendant made false certifications or false statements in the claims for payment. Because in many instances, the claims for payment were being made by students who applied for loans, and not by the defendant, itself.

So, contrary, Defendants' assertion as a starting point, the actual claims for payment in *Hendow* were not, themselves, expressly conditioned on compliance with federal statutes.

Instead, the governing statutes in *Hendow* established incentive compensation ban a condition the university's participation in the programs, on compliance with the incentive compensation ban.

And the statute and the regulations nowhere expressly state that payments or funding were conditioned upon compliance with incentive compensation ban. Rather, the statute said only that the university had to sign an agreement that would condition its participation in the program upon compliance with the rules prohibiting incentive compensation.

And, the regulations said the same thing. Neither of them expressly conditioned payment upon compliance with the incentive-compensation ban. Nor did the participation agreement that the university signed.

So --

THE COURT: I thought you couldn't participate if you violated that ban.

MR. FRIEDMAN: That's correct, Your Honor. And the defendant in that case made the argument -- much -- much like Defendant in this case -- that the applicable statute, in regulation and agreement, did not expressly condition payment, but --

THE COURT: But participation.

MR. FRIEDMAN: But rather, participation.

THE COURT: And that's a distinction without a difference. I understand that. But still, maybe you can conflate those two there, but that doesn't answer my question.

MR. FRIEDMAN: Well, Your Honor --

THE COURT: When the statement is made to a third party, whether you call it a participation condition or payment condition, that's where there's a difference between this case and all the Ninth Circuit cases.

MR. FRIEDMAN: But, Your Honor, in *Hendow*, the Court said three things that are critically important.

The first thing the Court said is that in looking whether a certification is a *sine qua non* of payment, the question is this: The conditions in that case, meaning participation -- and this is on Page 4 of Your Honor's booklet (As read):

"These conditions are also 'prerequisites' and 'the *sine qua non*' of federal funding for one basic

reason: if the Defendant had not agreed to comply with them, it would not have gotten paid."

So that's one critical point that is established by *Hendow*. In looking whether there's a prerequisite to payment, the Court looks to the -- if the Defendant would not have made the certification or made the agreement, would they have gotten paid ultimately. Took a very practical view.

So, as long as the Defendant's ability to ultimately receive payment depends upon compliance with a statute regulation, compliance with that is considered in the Ninth Circuit under *Hendow*, Your Honor, I believe, to be a prerequisite or *sine qua non* to payment.

The second thing --

THE COURT: What about if a corporation like the University of Phoenix has a deal with the government, performing some government contract, and one of the requirements is that they maintain good standing with their state corporate secretary, otherwise they can't operate? And they fail. For whatever reason, they commit some kind of violation, don't pay their right fees, or at least they make some kind of representation at stake about who's on the board, or whatever it is, that's false.

They're able to maintain their good standing and their ability to conduct business, but under false pretenses. And yet, they contract with the Federal Government. And the same

argument: They wouldn't have been able to participate; had they told the truth, they would have been not allowed to conduct any business in the state, wouldn't be able to exist.

MR. FRIEDMAN: That's right, Your Honor.

THE COURT: Is that the same thing? Is it still a condition of participation? If they hadn't lied, they wouldn't have been able to participate? Same kind of causation chain?

MR. FRIEDMAN: Well, two other things in *Hendow* -- and then I'll turn specifically to this case -- and why the facts of this case fall within *Hendow* were that the Court also recognized, given the broad intended reach of the False Claims Act, in addition to saying that if the defendant would not have agreed to the condition, they wouldn't have been paid, the Court also says it's a question of causation, I think as Your Honor put your finger on.

And the Court says -- and this is on Page 5 of the booklet -- that (As read):

> "The False Claims Act requires 'a causal rather than a temporal connection between fraud and payment'...if a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork."

So, again, the Court in *Hendow* looks at it as a question

of causation in that respect, too. And it looks to whether the certification was, in fact, a causal link in the chain of causation, ultimately to payment.

And the third thing that the Court said in *Hendow* which is particularly apt here is it rejected the notion that in a Medicare/Medicaid context, some explicit requirement of a condition of payment be made.

And that's Page 6, Your Honor, of the booklet. And what the Court said there is that (As read):

> "An explicit statement...is not necessary to make a statutory requirement a condition of payment, and we have never held as much."

Those three principles applied here, Your Honor, show exactly why the false certifications that were made in this case and the false representations that were made in this case qualify for treatment under the False Claims Act.

THE COURT: Well, the causal chain is one that interests me, because I start off with that. And that is in a case like *Hendow*, the causal chain is not hard to glean. You cannot have this financial incentive, you know, incentivize recruiters, et cetera, et cetera. Otherwise, you're out.

MR. FRIEDMAN: Right.

THE COURT: In this case, I understand the allegation that the FDA would not have approved the drug, had it been known of the various violations alleged of Gilead. But the

comeback to that is: Well, it's a little more complicated than that. It's not just a one-dimensional, on-off, zero-one, you know, kind of digital on-off. There are a variety of things that could have happened.

Had some of these things in the hundreds of pages of the complaint -- maybe some of those would have led to recall or disqualification of the drug, or non-approval. Maybe some of them would have led to some other action. Some delay or something else.

I've had many cases -- I've had securities-fraud cases involving FDA action on pharmaceutical labs where, my God, it took years, you know, to issue certain letters, and warning letters, and they got remedial action, and blah, blah, blah. To me, it seemed like it took forever. And they continued to sell the drugs, notwithstanding iron filings and everything else in the drug.

So, how do we know that that causal chain which is so obvious, so direct, so plain in *Hendow* would have applied here?

And I ask that question sort of rhetorically, because that raises the question of where that causal chain goes through into a bureaucratic box that's complicated, that's multi-pronged, and that's wide and deep that suggests: Well, maybe the FCA is not the proper venue.

MR. FRIEDMAN: But, Your Honor -- and I'll go back to

the causation issue, and show you exactly why the false-certification theory and the promissory-fraud theory are aptly applied in this case.

But the short answer to that question is that under the four-part test in *Hendow*: Requires a false statement, made with scienter, that is material, that leads to -- ultimately to payment.

And materiality under the False Claims Act is not judged based upon whether the government would or would not have actually approved a given drug or a particular facility. The test for materiality under the False Claims Act, both in the statutory language and in *Hendow*, is whether the certification or false statement had the tendency to influence the government's decision, or the capacity to influence the government's decision. Not what the government's decision ultimately was in the particular case.

So --

THE COURT: Which decision? Tendency to influence the payor's decision to pay?

MR. FRIEDMAN: Well, it depends on which stage of the causal chain you're going to.

THE COURT: Do you have any case that suggests that it's the mere tendency to influence the gatekeeper which then leads to the payor -- eligibility to go to the payor?

MR. FRIEDMAN: Well, the same thing is true in the

University of Phoenix case. There was no -- the point here is the -- there's certifications that are required under the statutory scheme for introduction of the new drug, and for introduction of the new facility.

And if you turn to Page 10, I've tried to show that progression in the causal chain that ultimately applies here. You have the new drug application which results, if it's granted, in approval of a new drug.

You have Synthetics China -- we use that as an example because that's -- much of the complaint is devoted to the Chinese facility that was not registered that they had the tainted API -- active pharmaceutical ingredient -- produced at.

(Reporter interruption)

MR. FRIEDMAN: "Ingredient."

The manufacturing process, and the introduction into commerce.

If you flip the page to 11, you'll see that we allege and there is evidentiary proof referenced in the complaint that there were false certifications made at every stage in that process, leading to the introduction into commerce of the tainted pharmaceuticals.

There was a false certification that was made in connection with the new drug applications. There were myriad false certifications that were made when Gilead was seeking to

qualify Synthetics China to move the manufacturing process there. And there were false certifications made in connection with the manufacturing process.

The FDA, the statutes, and regulations at each step say that you have to comply with the GMP standards, and you have to certify compliance with those standards as a precondition to introducing the drugs into the market.

So, if you turn -- those statutes are described at Page 12 with respect to adulterated drugs. But if you look at Page 13, what you have is an example of an express certification by Gilead at the new-drug-application stage. And there, they both certify and agree that they will comply with all applicable laws and regulations, including the good manufacturing practices that were violated here.

And we allege and provide evidentiary proof that at the time those certifications made, they were false. If those certifications were not made because they could not truthfully be made, because Gilead had no intention to comply with the manufacturing processes, then they're out of the box. They could -- as a matter of law, they could not apply, so it's not a question of whether the FDA would have approved it.

If they hadn't given the certifications because they're false, they could not have introduced the drug into commerce, it would not have been a covered drug under Medicare, and they would not have been paid.

So, it's not a question of whether, had they disclosed a particular subsequent violation, the FDA would have taken some different action. Here, at the outset, at the get-go, they have to give that certification, which was false.

The exact same thing is true, Your Honor, with respect to the Synthetics China plant.

THE COURT: When you say "false," it says:

"I agree to comply with all..."

"I agree to comply."

That's a promise of what they will do. Right?

MR. FRIEDMAN: Correct.

THE COURT: It's prospective.

MR. FRIEDMAN: At that point, it is. But look at Synthetics China, which is a critical link in this process.

With Synthetics China, again, when they decided they wanted to move to a cheaper Chinese facility which was unregistered, Section 356a of the United States Code required that before they can distribute the drug, they have to validate that it has the same quality, strength and purity as the NDA-approved drug from the existing manufacturing process. The regulations are to the same effect.

And, on Page 15, it just is guidance, it's a public record from the FDA that makes it clear that that that (Unintelligible) apply in the situation that we have here. When Gilead was going to move to this Chinese facility, a new

manufacturing plant, that kicked in the requirement that they demonstrate through validation testing that this new plant would be able to produce product with the same purity as had been approved in the NDA, the new drug application.

THE COURT: How do we know what the FDA would have done?

Let's say they found out sooner. Before allowing the manufacture and distribution, they then learned that: Well, wait a minute, they've been using Synthetics China before we approved or before this was brought to our attention.

How do we know what the FDA would have done then?

MR. FRIEDMAN: Well, what happened, though, Your Honor, is that they were required to file a document with the FDA called a "Prior Approval Supplement," a PAS. Which means in order to demonstrate the capacity of this Chinese facility to produce API with the same purity and strength, they had to submit a given -- a new document. And they did that.

And if you turn to Page 16 -- and again, I need to be a little careful here so I don't run afoul of the sealing order. But specifically Pages 16, 17, and 18, what the documents show is that in connection with this requirement -- again, it's not a question of whether the FDA would have approved the Chinese plant based upon what subsequently came to light, but when they submitted the PAS for Synthetics China, they lied. They

said that the test results showed that it was the same purity and strength as the preexisting facility's.

They submitted falsified test results in which, again, without going into the details, they certified that these test results did not show contamination, when in fact, the real test results did. And they certified on Page 18, once again -- this is a document by the way, Your Honor, from the FDA website. We have the actual one signed by Gilead.

But, the key is the certification. It's the same certification. They certified that they would comply with the good manufacturing processes, and that the information submitted to gain approval for the plant was, in fact, accurate.

But that wasn't the case. They had no present intention to comply with the good manufacturing practices because they knew, based upon the test results, that they could not, would not, did not qualify. So what you have here is not only a false express certification, but you have one that is false at the time it is made.

We're not talking about prospective actions, as Your Honor was concerned about. You're talking about the results of the tests they were required to conduct, as a requirement to distribute one capsule of this product. It was a presently-false statement that's relevant not just to the false-certification theory, but it's relevant to the

promissory-fraud theory.

It's one thing, Your Honor, to say: We intend to comply with these requirements. It's quite another thing to say -- to lie, and say: We are in compliance; here are the test results to certify compliance with these practices, when they know that they did not comply.

It's not a question of what the FDA would have done when they finally decide -- determine there's contamination. They could not file this application. They could not file the certification, because it was false.

And that's exactly the case, going back to *Hendow*, that's presented in *Hendow*. What the Court said in *Hendow* was the condition of payment or participation was that they had to file -- they had to certify -- actually, it wasn't even certification, it was simply an agreement, that -- acknowledging the incentive-compensation ban.

Here, what you're talking about is at the moment -- not only are they required to give the certification, but the certification given is false when made. That's why it doesn't -- we're not going to get into what the FDA would have done.

What we're saying is that you can't qualify yourself to participate in, ultimately, Medicaid and Medicare, by falsely certifying to the FDA that you are in compliance and will be in compliance with very strict manufacturing standards, when your own test results show that you're not in compliance, and

that that plant didn't have the capability of complying.

With respect --

THE COURT: So, had they truthfully -- had they been truthful, according to your view, they couldn't and would not have certified, signed this certification --

MR. FRIEDMAN: Correct.

THE COURT: And therefore, without certification, no approval.

MR. FRIEDMAN: Correct.

THE COURT: No discretion.

MR. FRIEDMAN: Correct. This is not a question of substituting a jury's discretion for the FDA's. This is a question of their -- they can't file the certification that is required, because what they did was lie. But, had they not lied, they could not file -- they couldn't have given the certification.

And if they went to the FDA and couldn't give that certification, they can't -- under the statutes and the rules, they can't sell any of these drugs. That's the critical point, Your Honor.

And, with respect to materiality, I would simply point Your Honor to the fact that the statutory standard for materiality is whether it has within the false claims statute -- is whether it has a tendency or the capability of impacting a decision by the government.

And a decision -- in the case law, a decision is not necessarily simply to pay. It's a decision whether to confer a benefit. And, here, the benefit, of course, is FDA approval of the product and the plant, which are absolutely required to sell the product and get paid.

Another case within the Ninth Circuit --

THE COURT: Wait; say that again? I thought the -- I'm not sure I caught that last point you were making.

MR. FRIEDMAN: Okay.

THE COURT: Say that again.

MR. FRIEDMAN: If you look at Page 22, which is a quote from *Hendow* on materiality, there's a statutory standard, as I mentioned, which looks at whether it has a tendency or the capacity to influence the government.

But what they say in *Hendow* is that (As read):

> "...the question is merely whether the false certification -- or assertion, or statement -- was relevant to the government's decision to confer a benefit."

What was the benefit that was actually being conferred in *Hendow*? It was eligibility to participate in the program, and ultimately receive payments.

What is one of the benefits that is being sought here? It's FDA approval to sell the product, which is absolutely necessary in order to gain payment.

If Your Honor would look at the *Amphastar* --

THE COURT: Well, we have a disparity between the benefit giver and the payor in this case that didn't exist in *Hendow*.

MR. FRIEDMAN: It didn't. But look, for example, at the *Amphastar* case, which is a recent case from the Central District, which Defendants do not address or deal with in their papers. That was a case involving off-label use of pharmaceuticals.

I'm sorry; the *Amphastar* case was a challenge, a patent case. It was a challenge by a competitor to a patent granted to the defendant.

And the false claim in that case, the false statement was made to the patent office, to secure a patent. That patent then allowed them to sell their drugs and get payment from the federal government under Medicare and Medicaid.

The allegation was that the patent was issued based upon false assertions to the Patent and Trademark Office. And that led to the issuance of a patent, which then allowed the defendant, according to the plaintiff, to charge inflated prices for their product.

So there's a case in which the false statement is being made to one agency, the patent office. The payments are being made, as in this case, by Medicare and Medicaid. And the judge in that case sustained the complaint, applying *Hendow*

and Ninth Circuit precedent.

So it's not a one-off case where there is a disparity between the agency to whom a false certification is submitted, and the payor, the agency ultimately making the payment.

With respect to --

THE COURT: I can see one difference. And that is: When the patent office acts, it either grants PATENT or doesn't. Ultimately. I understand there are interim steps.

MR. FRIEDMAN: Well --

THE COURT: It's a little more complicated when you are talking about what to do -- you know. Let's say the truth is learned about after the drug has hit the market, in terms of the decision to recall or not.

MR. FRIEDMAN: Well that's -- again, that's a subsequent decision, Your Honor. If you look at it at the critical point, which is the time that they're conferring the approval, just like granting a patent --

THE COURT: Aren't some of the allegations post-approval? Failure to comply with GMP and some other things post-approval?

MR. FRIEDMAN: There is conduct that is post-approval that is used as proof. But --

THE COURT: At least some of those get into the more complicated question of what would the FDA done, had it known.

MR. FRIEDMAN: Again, because of the all-or-nothing

approach that Defendant took in this case, we didn't get into every single aspect of -- every single claim that is alleged. I'm focusing on Synthetics China because that is a large part of it.

But with respect certainly to Synthetics China, again, the FDA -- there would be no approval, just as there would have been no patent application, if -- unless the certification was made, and the certification was false when made.

Omnicare, Your Honor, I submit, is far, far afield from this case for several different critical reasons. Of course, *Omnicare* is a Fourth-Circuit case, not a Ninth-Circuit case.

But, the difference in *Omnicare* is it's completely at odds with this case. In *Omnicare* there was no allegation that the Defendant made an express false certification at the outset, made an implied certification, or any false statement, whatsoever.

Here's what the District Court said in describing what the relator in *Omnicare* did not do. And, Your Honor, it's at Page 14, it's a Westlaw citation. It's at Page 14 of the Westlaw citation. And I quote it because I think it's an absolutely critical distinction between *Omnicare* and the case we're dealing with here.

What the Court says in *Omnicare* is, and I quote --

THE COURT: Are you quoting from the Fourth Circuit or from the District Court?

MR. FRIEDMAN: This is from the District-Court decision, which will be -- which is ultimately carried forth into the Fourth-Circuit decision, although the Fourth-Circuit decision is not as clear on the factual claims that are being made.

But --

THE COURT: Well, that's less important -- frankly, when an Appellate Court speaks, the fact are as they tell them to be, not -- that's the basis of the precedent.

MR. FRIEDMAN: I understand. I'll tie the two together for Your Honor.

But, what the District Court said was that, quote (As read):

> "In sum, Relator does not argue there was an affirmative false statement or false certification. Relator does not argue this Court should adopt the implied certification theory, and Relator does not argue the theory of fraud by omission."

So, and the Fourth Circuit picks up on that, because what the Fourth Circuit says ultimately in *Omnicare* is, and its holding is that (As read):

> "We conclude that once a new drug has been approved by the FDA and qualifies for reimbursement, the submission of a reimbursement request for that drug cannot constitute a false claim under the FCA on the

sole basis that the drug has been adulterated."

What happened in *Omnicare*, Your Honor, is this is the case where they had two operations. One was a repackaging facility, where they were repackaging drugs for sale in bubble packs so that elderly folks would receive a dosage that was necessary.

THE COURT: No, yeah, I understand that.

MR. FRIEDMAN: And there was no allegation in *Omnicare* that the defendant had submitted a false certification to gain approval of the facility at the inception. The only allegation in *Omnicare* was it turned out that they didn't comply with the manufacturing standards.

And what the Court said in the Fourth Circuit was, "Look. If all you have is the fact that ultimately there was a regulatory violation, that's not the stuff of which false claims are made."

But it's much different here, where what we allege is these certifications and agreements that were made on day one to allow the product to be sold were false, when made, and demonstrably so.

We have the documents. They are exhibits to the complaint, showing that those statements were false when made.

Furthermore, the Fourth Circuit in *Omnicare* doesn't even recognize implied certification theory whereas the *Ebeid* case adopted that theory in the Ninth Circuit, which may explain

why the relator didn't try to make the argument.

And to the extent that Defendants read *Omnicare* is as expressly -- as requiring the Medicaid or Medicare statutes to expressly condition payment on compliance with federal statutes, that's at odds with *Hendow*. And Page No. 6, where the Court specifically said that there is no requirement of an explicit statement pre-conditioning compliance.

So I would say, Your Honor, that *Omnicare*, apart from the fact it's out of this circuit, the critical distinction is there was no allegation of a false certification that was false when made at the inception that would give rise to either a false certification under the express or implied false-certification theory, or a promissory-fraud theory.

The relator could not allege and did not allege in *Omnicare* that the defendant in that case was able to open the facility on day one, based upon a false statement, representation or certification. It was something in happenstance that after the fact, there was there was a violation. There were not rampant violations the very day that the facility doors were opened, and there was no allegation of certification.

THE COURT: You've been patient. Let me hear the response, please.

MR. POSNER: Thank you, Your Honor.

Well, look. Your Honor's, I think, initial instincts were

correct. Obviously, there have been some courts that have struggled with this, and they have all dismissed these kinds of cases. The District Court in *Omnicare*, the Court of Appeals, even the *Alcon Labs* case in cert was denied, and *Omnicare* recently. I think all the cases --

THE COURT: Not the District Court in the *Amphastar* case.

MR. POSNER: Well, actually, yes. I was going to get to the *Amphastar* case. Actually, that case was dismissed. The relator's counsel, for some reason, said they sustained it. I'll read from the case here. And, actually, the *Amphastar* case actually shares a failing with this case. Okay?

One of the remarkable aspects of this case, Your Honor, you're correct that the Ninth Circuit cases involve misstatements to the payors. And what it also means is that those cases involved the contract between the payor, or the claim form, or the agreement, or the regulations about compliance.

Well, here, it is undisputed that neither the Medicare program nor the Medicaid program or any direct sales of these life-saving medicines to the United States government requires compliance with the manufacturing processes as a material precondition of payment.

How do I know that? Well, I know that in part because

Omnicare held that. But I also know that, more importantly for this case, because the relators concede that. And the reason they concede that is because we do not have before the Court the Medicare participation agreement, the Medicaid participation agreement.

They allege all these sales to the government of the United States of America. And they have not produced a single contract. And they have conceded that in none of those agreements or regulations or laws that there is any requirement to comply with the manufacturing processes that are alleged to have been violated.

And, what the Ninth Circuit cases -- and the *Amphastar* case -- just to finish this, the *Amphastar* case didn't have that either, and that's why the Court threw the case out, because the Court found Amphastar supplied no representative examples of false claims, they didn't provide the contracts, they didn't provide the basic agreement documents that would even allow you to determine materiality.

Hendow is an easy case, Your Honor, because the agreement that the Court was considering was the agreement with the payor. "I will sign an agreement with you, the payor. Here is my participation agreement. Here is my contract with you."

And the Court noted in *Hendow* that the agreement, as well as the statute, as well as the regulation, all expressly conditioned not just participation, but payment. And I am

quoting repeatedly from *Hendow* on the precise requirement the Defendant was alleged to have violated.

So, the *Ebeid* case, decided after *Hendow*, says the case -- the cases all impose material precondition of payment, Your Honor. They may speak slightly differently, but that's the rule that everybody is applying here. That's the rule that the Fourth Circuit imposes, and that's the rule that *Ebeid* imposes, *Hendow* imposes, and of course, *Hopper* imposes.

And in fact, both *Hopper* and *Ebeid* --

THE COURT: The rule being what?

MR. POSNER: Being that, you know, what you need -- the -- the -- the false representation or certification. And I'm not putting any talismanic significance on the word "certification." But the false statement in question, Your Honor, has to be a material precondition to payment.

That is the rule that flows through all of these cases. It flows through *Omnicare*, and it flows through three Ninth-Circuit cases. That's why *Hendow* is an easy case to decide. Because, *Hendow*, they had a statute, a requirement, and the contract between the parties (Indicating). That explicitly --

(Simultaneous speakers)

THE COURT: -- a material precondition of payment is that you have a valid drug.

MR. POSNER: Well --

THE COURT: Validly approved.

MR. POSNER: Your Honor, the reason we have the material-precondition-to-payment rule, of course, is to distinguish between fact patterns that go to claims for payment -- which the False Claims Act is limited to, obviously -- and an array of other regulatory issues that the government can deal with separately.

And that, that issue, Your Honor, is a factor in determining materiality. Both the *Hopper* case -- and even in *Hendow*. Obviously, *Hendow* distinguishes the Medicare context.

And Your Honor is already familiar: What are the other enforcement tools that the United States has at its disposal here?

Your Honor is familiar with a number of them: Consent decrees, warning letters, inspections, recalls, potential criminal liability. The United States has an array of remedies.

That's why the courts impose this gatekeeper material-precondition-to-payment rule, to limit claims under the False Claims Act. Because the claims, the statements have to relate to reimbursement or payment. They have to be material preconditions to payment and reimbursement.

So let's talk about -- because otherwise, obviously, Your Honor, we would be in this limitless morass of looking at every statement to the FDA involving drug approval, or

post-approval, or inspections or recalls. And a relator is going to say, "Ah, you lied there; you made a misrepresentation; that's a violation of the False Claims Act."

And the reason the courts impose this gatekeeper in the first place is to distinguish between material preconditions to payment and, obviously, other statements to the FDA that can be dealt with in an array of other ways.

All right. Now, there are several reasons why allegations that the FDA was duped does not work here. First, of course, none of the statements to the FDA had anything to do with payment or reimbursement. They're not material preconditions to payment. They had nothing to do with payment or reimbursement.

Even under the promissory-fraud theory -- which, by the way, *Hopper* says is very narrow -- but even under this theory, *Hendow* is clear: It has to be a material precondition to payment. These statements have nothing do with reimbursement or payment. Okay?

Now, how do I know that? Well -- and, Your Honor, I obviously don't have an objection to the extent these visual aids will be helpful. Obviously, the complaint allegations and the documents control.

The relator has submitted 29 exhibits to their motion to dismiss. There are only two statements to the FDA in there.

And as Your Honor has pointed out, they are statements that are part of a very long approval process and post-approval monitoring. Okay? They have nothing to do with payment or reimbursement. They have nothing to do with claims for reimbursement. It's not just that they don't use those word, although they don't. They just -- they are statements about submitting stability data. Or, "Here's some more data for your consideration."

And of course, Your Honor put your finger on one of the big problems with this theory is it -- the theory is predicated on the idea that: Well, they wouldn't have approved all these life-saving and life-preserving medicines if they had known this. Or: Well, okay, even if they had approved it afterwards, we didn't know this was all going on; we would have revoked approval.

Okay? And it's going to enmesh the Court -- as the Court is already thinking through, it's going to enmesh the Court in FDA approval and post-approval decision-making.

THE COURT: Except, as through the examples here that Mr. Friedman gives, that had the -- if you phrase it in terms of not what the FDA would have done had it known after the fact that the certification was false, but had there not been a false certification in the first instance, they wouldn't have even gotten -- there was no discretion. There would not have been an approval of the drug.

MR. POSNER: Well, there's no support for the idea -- I mean, there obviously are -- the complaint, itself, details a very complex drug approval process. Okay. It begins frequently with animal testing, goes to human testing, and clinical trials.

Your Honor is familiar -- the Code of Federal Regulations and the FDA regulations detail a very complicated drug-approval process with which Your Honor may be familiar. There are many, many submissions that relate to that. It is true that they have nothing do with payment or reimbursement. I think that's probably conceded.

But, Your Honor, there is no support for the idea that any of those submissions -- because of course what the relator is saying is all of those submissions are material, every single time you submit something to the FDA as part of the approval process, it's all material to get it approved, and then later payment happens.

Yeah, it's true that none of these statements were made, as Your Honor has put it, to the payor agency. That's certainly true. But what they're saying is that every single submission to get this product approved -- and as Your Honor knows, that takes years, and it's all laid out in federal law and regulations -- they are saying that every single one of those submissions is material.

And there is no legal support for that, whatsoever. It is

stretching the False Claims Act well past its ability to be limited to claims for payment.

The -- the vast majority of the exhibits that have been cited here, I think 27 of the 29, are internal statements that move the drug along in its manufacturing process.

How do I know that? Because Paragraph 34 makes that abundantly clear. Paragraph 34 says: Well, Gilead has a very complicated system for processing the manufacture of its life-saving products. There's manufacture of active pharmaceutical ingredient, then maybe sometimes it goes to a contract manufacturer, and there's lots of forms along the way. They lay all this out in Paragraph 34.

And so what they're arguing is: It's not just that those statements, Your Honor, weren't even made to the government. They're arguing that it's all material. And they're arguing that, even though it had nothing to do with claims for reimbursement or payment.

It's completely unlike *Hendow*, as I think Your Honor first imagined, that these are -- they're both internal statements that move the manufacturing process one step along. And Paragraph 34 says: Well, they have this really complicated process with all these forms.

And, we can take that as true. And the vast majority of the documents cited are those forms that move the product along in the process (Indicating). They are not even made to

the government. They're internal.

But more importantly, Your Honor -- I mean, that would be reason, alone, to not credit it. But, they have nothing to do -- how they be material preconditions for payment? They're not made to the payor, they aren't even made to any agency, and it has nothing to do with reimbursement.

THE COURT: Well, but there is a -- a causal relationship between getting FDA approval, and then ultimately being able to get paid for this drug by Medicare and Medicaid. Because without the approval, you don't have a drug to sell, and you don't get paid.

MR. POSNER: Yes, Your Honor. But there may be a number of predicates to getting the drug paid for. And even if the approval process is an important one, and I don't deny that it is, then every part of the approval -- that's exactly what *Omnicare* was worried about. That's why it said we need a gatekeeper rule here, that -- I mean, it's applying the same legal standard that the Ninth Circuit applies.

THE COURT: That does raise a question. Your comeback to that, Mr. Friedman, is: Well, look at this. No certification, you wouldn't have gotten it; we don't have to guess what would have happened.

But there are so many things along the way. You can imagine if they just faked one test result, and not anything else. Or if they had not disclosed two or three things here,

but everything else was okay. At some point, you have to engage in some guesswork, right, as to what the FDA would have done.

Or, are you carving out only the ultimate certification, where there's no FDA discretion? Is that the line where FDA has no discretion, and where they have discretion? Is there -- some areas where they do have discretion, but I take the after-market situation where there is a threat of recall because of some disclosure about impurities. There is discretion. You have to admit, there is a zone where we don't know -- zone of conduct where we don't know how the FDA would have responded.

How do I institutionally respond to that, as a court? Where it's not so clear that -- no certification, ultimate certification, no go, no approval? There are lots of larger gray areas.

And your rule is that: Well, even if the misrepresentation's not made to the payor but made to the licensing agency, which then leads to the payor eligibility, that can be an FCA claim.

And I'm asking you: What about those gray areas where there's -- not so clear what the FDA is going to do, would have done?

MR. FRIEDMAN: Several things, Your Honor.

First, there are certain discretionary aspects to FDA

approval, if it's relating to the efficacy of a drug or something like that, and there's a debate.

But what we're talking about here is a certification that is required, just as in *Hendow*, by statute and by regulation, that the company could not make truthfully, and made falsely.

THE COURT: I understand you're saying this is a clear case, certification. But I need to know the answer to this larger question, because if we open up this door, are we opening up a Pandora's box, with a slippery slope? I have to consider, as a judge, the slippery-slope problem.

So I'm asking you what is beyond the slope. What if there is a lie concerning efficacy? They faked a test, and it's not as quite as efficacious and they said it did, and the FDA went and approved it? Then we discover they exaggerated the effect. They didn't give a fair sampling, or something was not totally disclosed. And then, they get certificated, and they get approved, they get billions of dollars from Medicare, and now it's been disclosed.

Is that fair game for an FCA claim, once it's disclosed that they lied on an efficacy test?

MR. FRIEDMAN: I think, Your Honor, that that is a factual determination ultimately, that there needs to be the benefit of discovery, and there needs to be an opportunity to see exactly what the nature of the misrepresentation is.

And here, we're not --

THE COURT: And let's say you get that information, and then you still have to determine: What would the FDA have done.

If there's some discretion, does the Court sitting in an FCA situation, or a jury, have to ascertain and determine what -- whether the FDA would have approved anyway, or not approved, or done some other intermediate step?

MR. FRIEDMAN: Well, Your Honor, if, if it was a different case, I could envision a case where that might create a problem of undue speculation and intrusion.

But here, you're talking about a certification, a very specific false certification that was made with respect to test results and representations to the FDA that were false.

With respect to materiality, *Hendow* says, you know, that if you are looking at materiality, that it was an academic question where the statute and regulations explicitly condition participation in the program.

The Court said that: Look. If the statute, regulation and agreement explicitly conditioned participation and then ultimately payment on compliance with things like the precise requirement of the statute, then there's not a material -- the statute defines materiality.

THE COURT: Well, what's the condition here? The condition is FDA approval. Right?

MR. FRIEDMAN: For -- the condition for participation

in the Medicare program is that you have a covered drug. And the condition for approval by FDA is that you submit a certification, and that you comply --

THE COURT: Well, what's a covered drug within the meaning of the Medicare and Medi- --

MR. FRIEDMAN: It's one that's approved by the FDA. And so, that's why there's -- this is not an indirect causal chain. This is an absolute direct --

THE COURT: Right. But literally, it is approved. It shouldn't have been approved, arguably, but it was approved.

MR. FRIEDMAN: That's right. And I would agree, Your Honor, that if the question were a matter of discretion as to whether it should have been approved because it was safe or efficacious with respect to a new drug, that's one thing.

But here, where the statute requires that you get approval based upon validation tests showing that with good manufacturing processes, it has the same purity with respect to Synthetics China, where the statute specifically requires that you certify compliance with good manufacturing practices, this is not a situation where it's some gray zone of discretion.

THE COURT: What is the misrepresentation here made to the payor? Do you claim there is a misrepresentation, other than the misrepresentation to the FDA?

MR. FRIEDMAN: No. We do not say that Gilead, itself, made a direct misrepresentation to the payor. We do not.

But, I submit that under *Hendow*, that's not -- the question is not to whom the representation was made. The question is whether the representation was made, it was false when made, with scienter that was material in the sense that it may have influenced the government action. And conferring a benefit, which in this case is the FDA approval.

With respect to *Amphastar*, the Court did -- I misspoke. The Court did ultimately grant the 9b portion of the motion. But the Court endorsed the theory that there was false -- false statements under those circumstances in connection with the FCA.

The notion that there are these other tools that would be available to the FDA, that applied equally in the *Hendow* case. It applies in every case in which the government has multiple tools.

In the *Hendow* case, the government could have de-licensed the facility, the University of Phoenix. They could have brought enforcement proceedings against the university. In fact, they did bring enforcement proceedings under the Department of Education Act.

But that didn't ultimately affect the fact that the relator stated a claim, and the statement of interest filed by

the United States government in this case makes that amply clear, as to the cases cited there: That just because the FDA may have other tools available does not mean that there's not a False Claims Act violation.

And, it certainly does not mean that the government should be constrained to pay for drugs which are so contaminated they never should have been approved in the first place, based upon a false certification.

THE COURT: You are asserting also in addition to false certification, a worthless services or -- another theory, right?

MR. FRIEDMAN: We make a factually false --

THE COURT: Factually false.

MR. FRIEDMAN: -- claim as well. That, I think, Your Honor, we didn't brief that extensively because I think that the more apt theories are false certification, express or implied, and promissory fraud.

But more importantly --

THE COURT: And the promissory fraud is -- could you articulate that one more time?

MR. FRIEDMAN: Sure, Your Honor. If you make a false certification, as Gilead did here, that you are in compliance and will be in compliance, and are manufacturing and will manufacture pure drugs that meet the specifications, and that's false when made, and is intended to gain approval, then

subsequently, the product sales and payments are all tainted. They're all --

THE COURT: So that's the promissory fraud made, at least in the first instance, to the FDA.

MR. FRIEDMAN: Correct. And I would point out, Your Honor, that in *Hendow*, the court said none -- those are different theories. But the court articulated a very specific four-part test that it said applied both to certification and promissory fraud. And, the elements of that test are amply demonstrated here. At all levels.

THE COURT: All right. Response?

MR. POSNER: I think Your Honor can dismiss this case, and write it narrowly. Okay? I think this is a straightforward application. I think we all agree that the legal standard is a material precondition of payment. All right?

I don't think the Court needs to hold that no submission ever to the FDA can't count. But, the allegations here -- they're only a couple to the FDA -- have nothing do to do with payment or reimbursement.

They -- it's not just that they don't have that, Your Honor. I want to come back to something that also is remarkable about this case. It's not so much that the relators are conceding that there was no misrepresentation ever made to the payor. That's a significant concession.

But, we have more than that. They haven't even elucidated: What are the rules of reimbursement; what are the conditions of reimbursement?

I think Plaintiffs' Counsel was almost about to talk about some off-label promotion cases which he cites. He's not -- I just want to point out, Your Honor, the distinguishing factor in those cases is, as the courts specifically noted there, those cases are based on Medicare eligibility rules like reasonable and necessary or experimental. There are Medicare rules and regulations and conditions of payment that guide the courts in those cases.

You have none of that here. You don't even have the agreements with the United States. You don't have the Medicare agreement, the Medicaid agreement. And that's because the relator concedes that there's nothing to do with manufacturing compliance in any of that.

And that's why this is a remarkable False Claims Act case, because all of that is absent here. It's not just that the misrepresentations were made to a completely different analysis. It's not just that, you know, there is no misrepresentations that are made to Medicare and Medicaid. It's that you don't even have before you the basic contract or eligibility reimbursement and payment rules to govern your analysis.

And I think that's what's very unusual about this case.

And that's why this is a straightforward easy application of the material-precondition-to-payment rule that the internal documents that make up the vast majority of the exhibits here have nothing to do with payment or reimbursement. And the couple of statements to the FDA have nothing to do with payment or reimbursement.

That's an easy application to the rule. And, obviously, open -- to rule otherwise would open up every representation to the FDA that was part of the approval process.

To the extent the relators are saying somehow that if you make a mistake or you're fraud on filing No. 64, that that somehow removes the discretion from the FDA, or that there's more discretion or less, there's just nothing in federal law that provides that.

There are lots of filings that make up the drug approval process. This one, they've only pointed to two among many, and it has nothing to do with payment or reimbursement.

THE COURT: Let me ask whether the government -- Ms. Winslow, do you have any comments to add from the government's perspective?

I mean, I did receive the statement of interest, and I want to know, since the U.S. has an interest in this --

MS. WINSLOW: Yes, Your Honor. Thank you. I would like to make a few short points.

First of all, I just want to make clear that the

government's interest here is not in this -- in the outcome of this particular case. And we're not commenting on the allegations or defenses in this particular case. But we're interested in the -- mostly in the development of the False Claims Act case law, which is why I'm here today.

We are the real party in interest in this case. But that's not why -- that is not the main purpose of what I'm about to say.

So, from our point of view, the point isn't what the FDA would have done if it knew about alleged misrepresentations. It's whether the alleged misrepresentations or the alleged defect in the manufacturing process or the alleged defects in the drugs, themselves, were material to the federal healthcare program's decision to pay.

And, it's not accurate that there's nothing in the Medicare or Medicaid rules that have to do with drug manufacturing. There may not be anything specific to drug manufacturing, but the federal healthcare programs will not pay for a drug if it's not approved by the FDA.

And, it cannot be that mere FDA approval precludes any False Claims Act liability. For example, I mean, I can think of a lot of -- I can give you a parade of horribles, but I'll just throw out a few examples.

If, for example -- Your Honor talked about misrepresentations from clinical testing. If, for example,

there were clear -- if the company tested the drug, and this clinical trial came back and said the drug doesn't work, but the company falsified the documents from the clinical trial to say that the drug did work, I don't think there's anyone here -- and the FDA then approved the drug on that basis, I don't think there's anyone here --

THE COURT: See, you're making the converse. That is, not that the claim is based on FDA being duped into granting approval, but that you can have a worthless drug or non-safe drug, or a dangerous drug, or a drug that doesn't meet what it's supposed to do, notwithstanding FDA approval, and FDA approval does not preclude - I guess it sounds like a factually-false claim under the FCA.

MS. WINSLOW: Yes, Your Honor. And there could be lies to the FDA that caused the FDA to approve a drug that are so material that there's no one who could argue that the FDA would have approved the drug, had it known it to be true. And if the FDA had not approved the drug, Medicare and Medicaid wouldn't pay for it.

Another example in the manufacturing area, an extreme example would be: So the FDA approves the manufacturing process, but then the company, when manufacturing the drug, adds something toxic to the drug. And it kills the Medicare patients who take it. I don't think there's anyone who would argue that Medicare was -- properly paid for that drug, and

that that shouldn't be a False Claims Act case.

THE COURT: All right. So, I understand the government's position that a drug can be materially defective, dangerous, and if submitted for payment without disclosure, that could constitute an FCA claim, even though that drug had somehow gotten approval.

Do you have any position on the argument that committing misrepresentations to the FDA in order to get approval can, itself, constitute an FCA claim?

MS. WINSLOW: Well, Your Honor, the falsity -- the misrepresentation to the FDA is one thing. But the falsity to Medicare or Medicaid or whatever the paying agency is is something separate. And that's that -- that relator's counsel stated that they are not alleging that there's a misrepresentation to the payor.

But, if this were a case that the government were proceeding with, our theory would likely be that there would be an implied false certification to the payor, that was caused by the drug manufacturer. It's made by whatever entity or individual that's getting payment from Medicare and Medicaid.

And that's the theory that the government has pursued and the courts have endorsed in the off-label marketing arena.

THE COURT: All right, but we have, I think, a concession that there is no claim of a misrepresentation

direct to the payor in this case.

MS. WINSLOW: And I don't think that there are any -- any communications between a drug company and Medicare and Medicaid, typically. But, the False Claims Act covers false claims and false statements that the defendant causes to be made, not just the direct statements and claims that the defendant makes, itself.

THE COURT: So what was caused here? What is the causation?

MS. WINSLOW: So here, just again, speaking in the abstract and not about these particular facts, a drug manufacturer that, say, put something toxic in the drug that was not approved in the FDA approval process, then provides the drug to a pharmacy or a hospital or an individual that then bills Medicare. The individual or hospital or pharmacy that's billing Medicare is impliedly certifying to Medicare this drug is valid, it is approved by the FDA, it is valid for reimbursement.

The manufacturer that put the toxic substance in the drug caused the biller to impliedly make a false certification. And that --

THE COURT: And the false certification has to do with the safety of the drug?

What is the false certification by the biller?

MS. WINSLOW: It could be the safety; it could be the

efficacy. Whatever the defect is. If it's something toxic, it would --

THE COURT: And that's implied. It's not expressed.

MS. WINSLOW: Correct, Your Honor, because the biller doesn't sign something saying "This is FDA approved and payable."

But that's exactly what happens in the off-label marketing cases, such as the *Scios* case that we cited in our brief that Judge Breyer decided.

The drug manufacturer isn't the one billing Medicare. In that case, it was doctors and hospitals that were billing Medicare. But, it's the drug manufacturer that caused the billers to make an implied certification to Medicare that these drugs were proper to be reimbursed.

THE COURT: Because they're being used not for the purpose alleged?

MS. WINSLOW: Correct. Well, they're being used not for a reimbursable purpose.

THE COURT: Let me clarify from you, Mr. Friedman, you have heard the government's view, but it sounds like you're not making that claim here.

MR. FRIEDMAN: Your Honor, when I responded -- I was attempting to respond to your direct question, which is whether we claim that Gilead, itself, made false representations to the payor.

Ms. Winslow is absolutely correct that a statutory scheme applies where the defendant caused another to submit a false claim.

And, in this case, just by way of example, if it turned out, and we allege, for example, that certain of these drugs contain arsenic, which is poisonous, if we ultimately prove at trial that there were drugs that were tainted in that fashion, that did not comply with the FDA approval, that Gilead intentionally released into commerce knowing and intending that the pharmacies and physicians who are prescribing the drug or selling the drug under those circumstances, that that is within the statutory language that says if you cause -- knowingly cause another to submit an express or implied false claim for payment, that's actionable.

THE COURT: So, what is the false claim that these are -- impliedly that these are -- sort of like a warranty of merchantability, that these are safe drugs?

MR. FRIEDMAN: Well, again, it would be a situation -- the question really boils down to -- comes back to materiality. And with respect to that type of claim, what was -- was the drug materially lacking in quality, purity, or efficaciousness, such that the approval, when granted, Gilead knew that that tainted product was going to be --

THE COURT: Let's say everything was fine, but after the approval, they put arsenic in there. Is there a false

claim there?

MR. FRIEDMAN: I would certainly say yes.

THE COURT: So, what is the false representation? Is it based on an implied representation that: Our product is safe? Is that the basis?

MR. FRIEDMAN: Implied representation that the product conforms with the conditions on which approval was granted, which include that it will be produced in conformance with good manufacturing practices. And, that it will be free -- be non-adulterated. It won't be contaminated.

THE COURT: All right. Do you have any dispute that the drugs were -- were -- put aside --

MR. POSNER: Right.

THE COURT: -- the fraud and inducement and all that sort of stuff, promissory fraud. But just, you know, adulterated drugs. They knew it, after approval process, they sold a bunch of adulterated drugs.

MR. POSNER: Well, I mean, *Omnicare* literally holds that -- the products that violate the good manufacturing practices, I think the United States would say, by definition, are adulterated.

The Fourth Circuit already held that adulterated products -- the mere fact that they are adulterated is not enough to be a violation of the False Claims Act. May violate other statutes. You may get a warning letter; you may get the

Justice Department investigating; you may get lawsuit --

THE COURT: You don't buy into the implied warranty that when a drug manufacturer sells drugs to a pharmacy that seeks reimbursement from Medicare, knowing it is non-efficacious or they substituted a placebo -- let's go to that extreme. It's a fake. You say there's other remedies, but no False Claims Act.

MR. POSNER: A couple of points.

(Reporter interruption)

MR. POSNER: Sure.

The answer is yes, I dispute that. The Ninth Circuit has never recognized that kind of implied-false-certification case. Number one.

Number two, the United States asserts in its brief that: Well, anything that affects sort of the strength or stability or purity might be enough. And they cite for that proposition, one case. And they cite the *Hendow* cause for that.

Now, there may be cases that support that proposition. But *Hendow* -- and I'm not aware of any, but *Hendow* is most definitively not one of those cases. There is no support in this district or in this circuit for such a hazy implied-certification case.

Now, then, Your Honor asked me a separate question. There -- there -- you know, there are some very, very narrow cases

that deal with what are called "worthless services." All right? I don't -- I don't take the relator -- maybe the relator's arguing that now; I'm still not sure. They've not argued that -- that's not a theory of their complaint, which I think is the operative document.

You know, if you -- if you sell something that's completely worthless, there -- you know, the cases really cabin something like that. As the Seventh Circuit famously said earlier this year: The product can't be worth less. The product has to be essentially completely worthless. There's essentially no support within the Ninth Circuit for this theory.

But even if there would be, Your Honor, A, the relators have never alleged this kind of theory, because it would require them to show the product was completely not efficacious, which is counter-factual, since millions of people have taken these products and millions of lives have been enhanced and saved.

There's no evidence, Your Honor, that the government purchased or reimbursed any of these batches that were supposedly worthless, all right?

You know, the few cases on this have also injected Rule 9 specificity principles into this. You know, you can't just say: Well, this batch had some problems in some specs, so you know what? I think they all have these problems. And you

know what? They were all worthless.

And the courts say this is a very narrow theory. I don't think Your Honor has to rule on this. In fact, in *Omnicare*, the Court said "I don't..." I think both the District Court and certainly the Fourth Circuit said, "I don't need to go there." All right?

And I don't think you need to rule on that, either. I think Your Honor can write a very narrow holding. I don't think -- to the extent the government is arguing for some really broad implied-false-certification standard, there's no support for that in this circuit, and *Hendow* is certainly not support for that.

I don't think Your Honor can straightforwardly apply the material-precondition-to-payment standard on these particular allegations. You know, the relators are not asserting, I don't believe, a worthless-services doctrine. There is no need for the Court, I think, to consider that. It's very narrow and cabined.

And, you know, you'd have to show which particular lots -- you have to trace it to lots the government bought or reimbursed. You'd have to show that they were completely worthless. And the Rule 9(b) principles would apply as I think other courts have. So I think Your Honor can write this very narrowly.

THE COURT: All right. I'm going take the matter

under submission at this point, and study the cases a little more carefully.

Thank you.

MR. POSNER: Thank Your Honor.

MR. FRIEDMAN: Thank you, Your Honor.

MS. WINSLOW: Thank you, Your Honor.

(Conclusion of Proceedings)

CERTIFICATE OF REPORTER

I, BELLE BALL, Official Reporter for the United States Court, Northern District of California, hereby certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/ Belle Ball

Thursday, October 30, 2014

Belle Ball, CSR 8785, CRR, RDR